IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., GILEAD PHARMASSET LLC and GILEAD SCIENCES LIMITED,

Plaintiffs, Defendants, Counterclaim Plaintiffs, and Third Party Plaintiffs.

v.

ABBOTT LABORATORIES, INC., and

Defendant, and Third Party Defendant.

ABBVIE INC.,

Defendant, Plaintiff and Counterclaim Defendant.

C.A. No. 13-2034-GMS

(Consolidated with C.A. Nos. 14-209, 14-379)

[redacted]

REDACTED VERSION

JOINT STATUS REPORT

In accordance with Rule 16(b) of the Federal Rules of Civil Procedure and Local Rule 16.1, Plaintiffs, Defendants, Counterclaim Plaintiffs and Third Party Plaintiffs Gilead Sciences, Inc., Gilead Pharmasset LLC and Gilead Sciences Limited (collectively "Gilead"), and Defendant and Third Party Defendant Abbott Laboratories, Inc. ("ALI") and Defendant, Plaintiff and Counterclaim Defendant AbbVie Inc. ("AbbVie") submit this Joint Status Report, with disputes noted. Counsel for the parties participated in a telephone conference as required by the Fed. R. Civ. P. 26(f) on July 31, 2014, and follow-up conferences thereafter. Fish & Richardson participated on behalf of Gilead, and Finnegan and Morris Nichols participated on behalf of AbbVie and ALI.

As noted below, the parties have disagreements with respect to: (i) narrowing of the issues (Section 4); (ii) the proper parties (Section 7); (iii) discovery (ESI framework and the procedure for resolving disputes) (Section 8); and (iv) schedule (Exhibit A).

1. Jurisdiction and Service.

The parties agree that the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 100, et seq. The parties also agree that the Court has personal jurisdiction over the parties for this action. No parties remain to be served.

2. Substance of the Action.

This is a consolidated action with claims for declaratory relief of patent invalidity and unenforceability and state law causes of action as described herein. It is also an action for willful patent infringement. The patents-at-issue are U.S. Patent Nos. 8,466,159 ("the '159 patent"), 8,492,386 ("the '386 patent"), 8,680,106 ("the '106 patent"), 8,685,984 ("the '984 patent"), and 8,809,265 ("the '265 patent")[1].

Gilead alleges that the '159, '386, '106, '984, and '265 patents are invalid and unenforceable; as noted below, Gilead intends to amend its pleadings to assert declaratory judgment claims on non-infringement. Gilead also alleges that AbbVie and ALI have injured Gilead in violation of California Business and Professional Code Section 17200, California common law of Slander of Title and Illinois Contract law.

AbbVie alleges that Gilead willfully induces infringement of the '159, '386, '106, '984, and '265 patents by marketing and sale of Gilead's fixed dose combination of sofosbuvir and ledipasvir, Harvoni®, to treat patients with Hepatitis C. Gilead has denied that it induces

[1] The '265 patent issued after the pleadings in this case were filed, but the parties have agreed to add this patent to the case with the Court's permission.

infringement of any asserted claims. AbbVie and ALI have moved to dismiss and strike all of the state law claims, which motion is fully briefed. (*See*, D.I. 35, 36, 38, 42, 48.)[2]

3. Identification of Issues.

The issues to be decided are:

(a) the proper construction of disputed claim terms in the asserted claims of '159, '386, '106, '984, and '265 patents;

(b) the validity and enforceability of the '159, '386, '106, '984, and '265 patents;

(c) whether AbbVie and ALI violated the California Business and Professional Code Section 17200;

(d) whether AbbVie and ALI violated the California common law of Slander of Title;

(e) whether AbbVie and ALI breached [redacted] in violation of Illinois contract law;

(f) whether Gilead is entitled to any damages or enhanced damages for its state law causes of action;

(g) whether an injunction should be entered against AbbVie and ALI for their violation of the state law causes of action;

(h) whether Gilead should be awarded its costs, expenses and/or reasonable attorneys' fees;

[2] AbbVie notes this briefing supersedes and replaces the motions and briefing at D.I. 13, 14, and 16. The new briefing was necessitated by Gilead's First and Second Amended Complaints (D.I. 25 and 31), which dropped certain state law claims. In addition, the parties have agreed that a decision on D.I. 35 and 36, will resolve AbbVie's motion to dismiss Gilead's counterclaims in the consolidated suits. *See* 14-209, D.I. 23 and 25; 14-379, D.I. 24, 25. Thus, the only outstanding motions for the Court are 13-2034, D.I. 35 and 36.

(i) whether Gilead has infringed one or more valid claims of the '159, '386, '106, '984, and '265 patents;

(j) whether Gilead's infringement of the '159, '386, '106, '984, and '265 patents is willful;

(k) whether AbbVie is entitled to any damages or enhanced damages;

(l) whether an injunction should be entered against Gilead for patent infringement; and

(m) whether AbbVie should be awarded its costs, expenses and/or reasonable attorneys' fees.

4. Narrowing of Issues.

AbbVie's Position: This is a patent case. AbbVie has filed a motion to strike and dismiss Gilead's state law claims, which are based solely on AbbVie's alleged conduct at the Patent Office. That motion has been fully briefed. (*See, supra*.) Moreover, in addition to being legally improper, Gilead's state law claims lack substantive merit. For example, the PTO considered the allegedly "withheld" information before issuing the majority of AbbVie's patents, and the limited and [redacted]

Should the Court deny this motion, AbbVie will request bifurcation of these claims for trial. Because Gilead's state law claims overlap completely with its inequitable conduct claims, which are claims for the Court to decide, the state law claims should be tried only after the Court's consideration of the inequitable conduct claims (which AbbVie further submits should be tried to the Court and separately from the jury trial on the patent validity and infringement claims).

ALI's Position: ALI contends it is not a proper party and will seek to be removed from the case. ALI, which is a subsidiary of Abbott Laboratories not AbbVie Inc., does not and has never had any involvement in the allegations in the pleadings. ALI has no interest in the patents-in-suit, the hepatitis C therapies at issue, or the contract Gilead alleges was breached. Gilead's complaint appears to confuse ALI with a separate company, Abbott Laboratories; yet after this mistake was repeatedly pointed out to Gilead, Gilead refused to drop ALI from the case. For the reasons explained in Section 7, Abbott Laboratories is also not a proper party.

Gilead's Position: This is not simply a patent case. [redacted].

Efficiency in this case will be fostered by having one trial. Gilead's state law claims do not "completely overlap" with its inequitable conduct claim. While certainly discovery will be relevant to both patent and state law claims, bifurcation would be inefficient and a poor use of the Court's limited resources. With regard to inequitable conduct, the Court can charge the jury and take an advisory verdict or render its own judgment separately, particularly since the testimony on inequitable conduct will overlap with that on patent invalidity.

Abbott Laboratories—in some corporate form—is the party that is liable for the conduct complained of through at least the 2013 division of Abbott Laboratories into two companies.

AbbVie says that Gilead has named the wrong corporate form. If that is established in discovery or through an acceptable stipulation, then Gilead will amend its pleadings as needed.

The parties expect that, as discovery proceeds and the case progresses, they may be able to narrow the issues before the Court.

5. Relief.

Gilead's Position: Gilead seeks restitution and damages for Defendants' unlawful conduct in violation of the state law causes of action discussed forthwith, as well as a declaration as to the invalidity, non-infringement and unenforceability of the '159, '386, '106, '984, and '265 patents, which claim therapies using combinations of Gilead's sofosbuvir and ledipasvir compounds. Gilead is not currently seeking a preliminary injunction but is seeking a permanent injunction against any further attempts by Defendants to claim methods of treating HCV using combinations of Gilead's sofosbuvir and ledipasvir compounds. Gilead also seeks recovery of its attorneys' fees due to the exceptional nature of this of this case, in accordance with 35 U.S.C. § 285.

AbbVie's Position: AbbVie seeks lost profits and reasonable royalty damages for Gilead's infringement of the '159, '386, '106, '984, and '265 patents, which claim a novel method of treatment of the Hepatitis C virus using combinations of direct acting antivirals, for short durations without interferon. AbbVie seeks enhanced damages, because Gilead's infringement is willful. AbbVie also seeks recovery of its attorneys' fees due to the exceptional nature of this case, under 35 U.S.C. § 285. AbbVie is also seeking a permanent injunction. AbbVie and ALI seek their legal fees under the California anti-SLAPP ("Strategic Lawsuit Against Public Participation") for defending against Gilead's current state law tort claims and for defense against the state law claims Gilead dropped after AbbVie's original anti-SLAPP motion

as stated in AbbVie's motion to strike (D.I. 39 at 6). If Gilead does not promptly dismiss all claims against ALI, ALI intends to seek fees for its baseless inclusion in this lawsuit.

6. Amendment of Pleadings.

AbbVie's Position: AbbVie will seek the Court's permission to supplement its complaint to add the newly issued '265 patent, to add its exclusive licensee AbbVie Bahamas Ltd. as a party, and to convert its claim for a declaratory judgment of infringement to a claim for infringement now that Gilead actively infringes AbbVie's patents. AbbVie proposes any motions to amend the pleadings be filed by **February 27, 2015.**

Gilead's Position: Gilead expects to amend its complaint to add declaratory judgment claims of invalidity, unenforceability, and non-infringement for the newly issued '265 patent. Gilead also expects to amend its complaint to add non-infringement defenses for all asserted patents now that its drug product has been approved by FDA. Gilead proposes that motions to amend the pleadings shall be filed by **June 30, 2015**.

7. Joinder of Parties.

AbbVie's Position: AbbVie seeks to add its exclusive license AbbVie Bahamas Ltd. to the case. AbbVie will oppose any attempt by Gilead to add Abbott Laboratories. On January 1, 2013, Abbott Laboratories separated into two companies, Abbott Laboratories and AbbVie Inc. AbbVie Inc. assumed all assets and liabilities for all research-based pharmaceutical programs, including the Hepatitis C program at issue in these cases. These assets and liabilities include all rights with respect to AbbVie's Hepatitis C drugs, all rights with respect to the patents in suit, and all rights and liabilities [redacted] In pharmaceutical cases filed prior to the separation of Abbott and AbbVie, this Court has ordered AbbVie Inc. substituted for Abbott Laboratories. *See, e.g.*, *AbbVie Inc. et al. v.*

Hospira Inc., No. 11-648 (GMS) (D. Del. Apr. 10, 2013).[3] Thus, Abbott Laboratories is not a proper party to this case.

AbbVie proposes all motions to join parties to the pleadings be filed by **February 27, 2015.**

Gilead's Position: Gilead expects to seek to add Abbott Laboratories as a party to this case if discovery or an acceptable stipulation confirms that it is the proper party. AbbVie and Abbott Laboratories were a single company until January 1, 2013. According to AbbVie's counsel, [redacted] Abbott Laboratories is the entity that originally pursued the patent prosecution strategies that are a central issue in this case with regard to certain of Gilead's patent and state law claims – its liability to Gilead is not extinguished through the corporate transaction that created AbbVie. Indeed, at least one Court has denied AbbVie Inc.'s request to be substituted for Abbott Laboratories. *See, e.g.*, *Roxane Laboratories, Inc. v. Abbott Laboratories*, Civ. No. 12-cv-312, 2012 WL 5511138 (S.D. Ohio Nov. 14, 2012).

Gilead has no information as to the propriety of AbbVie's proposed amendment of AbbVie Bahamas, Ltd. at this juncture.

[3] The single case cited by Gilead denying substitution of AbbVie for Abbott did so *prior* to the split and *prior* to the final November 28, 2012 Separation and Distribution agreement. The court denied substitution because "[t]he assignment agreements attached to *Abbott's Motion to Substitute* and *Abbott's Reply* are redacted such that the Court is unable to determine if AbbVie has assumed liability . . ." *Roxane Laboratories, Inc. v. Abbott Laboratories*, Civ. No. 12-cv-312, 2012 WL 5511138, *2 (S.D. Ohio Nov. 14, 2012).

Gilead proposes that motions to add additional parties to the pleadings shall be filed by **April 30, 2015**.

8. Discovery.

Status: The parties have exchanged requests for production of documents and interrogatories and responses thereto and will be proceeding with document production shortly. The parties' respective positions on a proposed schedule pursuant to which fact and expert discovery shall be conducted is attached hereto as **Exhibit A**.

Expert depositions: Unless otherwise stipulated or ordered by the court, depositions of experts are limited to one (1) day of seven (7) hours with each expert.

Certain current disputes:

1. *Electronically Stored Information*:

AbbVie's Position: The parties agreed at the outset of discovery that some electronic searching of files was appropriate, but disputed how discovery of ESI should proceed, particularly how many custodians' files should be searched and the search terms to be employed. The parties months ago tried, but did not agree on, an alternative framework to the Delaware Default Standard, and each party proposed search terms and custodians that it intended to search. Based on this, AbbVie proceeded to extensively search and collect ESI from the files of all the custodians it believed in good faith were appropriately searched and using search terms that it likewise determined in good faith were appropriate. We understand that Gilead has proceeded similarly.

Accordingly, at this juncture, Abbvie submits that there should be no need for the Court or a Special Master to have to expend valuable resources to address search terms or custodians. AbbVie further submits that the best way for the parties conduct the remainder of needed

discovery, including depositions, and to get to trial on the merits would be to move forward rather than having the parties redo their already conducted extensive searches or otherwise add further impediments. AbbVie does suggest that it would be helpful for the Court otherwise to include the typical provision in the Scheduling Order that the Delaware Default Standard will apply unless the parties agree otherwise, as this will confirm the proper framework for other aspects of ESI discovery such as the format for production.

Gilead's Position: Gilead has requested that AbbVie search the files of approximately 30 individuals: (i) the eleven (11) inventors of the patents-in-suit; (ii) the 2-3 (or more) individuals who participated in the prosecution of the patents-in-suit; and (iii) [redacted]. AbbVie has not agreed to do so. With respect to search terms, Gilead agrees there is no need to engage in a lengthy process involving the Court over search terms. If discovery reveals a deficiency, the parties can supplement the document productions.

Gilead does not agree to the limitations set forth in the Default Standard and submits that reference to the standard in the scheduling order will only confuse issues. As to the particular issue AbbVie raises about the format of the productions, the parties have begun producing documents and format has not been a problem.

2. *Limitations on written discovery and depositions*:

- Interrogatories: The parties agree that each side shall be permitted 40 interrogatories to the other side.

- Requests for Admission: The parties agree that each side shall be allowed a maximum of 70 requests for admission to the other side and 150 for the purpose of authenticating documents.
- Requests for Production: The parties agree that each side shall be allowed a maximum of 300 requests for production to the other side.
- Depositions of Parties:
    - The parties agree each side shall be limited to a maximum of 20 fact depositions (including party and non-party witnesses) and an additional 21 hours of 30(b)(6) deposition.
    - The parties agree that no witness shall be deposed for more than 7 hours unless otherwise stipulated or ordered by the court for good cause. The parties agree that any witness who appears on a trial witness list who has not been deposed will be deposable for 4 hours not withstanding any deposition limits.

3. *Resolution of discovery disputes*:

Gilead's Position: Gilead submits that this case concerns the intellectual property rights to revolutionary drug therapy that will cure a deadly disease that impacts millions of people worldwide. Gilead anticipates given the importance of the technology that there may be more discovery issues in this case than in the typical patent case, and respectfully suggests that appointment of a special master would remove from the Court some of the burden of addressing these disputes.

Because the parties are in litigation over this technology in a number of foreign countries, Gilead has filed and may file additional requests under 28 U.S.C. § 1782 for assistance in foreign proceedings. Gilead has included provisions in the draft Protective Order that will permit

appropriate use of discovery material overseas, and that such provisions will reduce or eliminate the need for filing section 1782 requests. Regardless of whether requests for discovery in aid of foreign proceedings originate through section 1782 filings or an agreed upon Protective Order, Gilead believes that use of a special master may be of assistance to the Court in reducing the burden on the Court.

To be clear, Gilead is not, as AbbVie states below, asking the Court to supervise foreign discovery disputes. Gilead is asking for the opportunity to provide some of the same information to the foreign tribunals that the Court and jury in this case will hear, as further described in its separately-filed section 1782 request.

AbbVie's Position: AbbVie agrees that the patents-in-suit cover revolutionary drug therapy. Like numerous other important pharmaceutical cases handled by this Court, AbbVie requests that this Court manage discovery disputes in accordance with the Court's standard procedure. AbbVie submits that the burden on this Court can be reduced by allowing foreign discovery disputes to be handled by the foreign tribunals hearing the underlying dispute. Gilead recently brought a 1782 action seeking this Court to supervise discovery for over a dozen foreign actions brought by Gilead in four different countries. Gilead states above that apparently it may bring additional 1782 actions. For the reasons stated in AbbVie's opposition to Gilead's 1782 action (*see* Misc. No. 14-243 (GMS), D.I. 4), AbbVie requests the Court deny Gilead's 1782 action and that the Court deny Gilead's request to enter a protective order that mandates that this Court supervise foreign discovery.

9. Estimated trial length.

Gilead's Position: Gilead estimates that a trial of the entire case would take approximately ten (10) days and seeks a trial in September 2016, if the Court's schedule permits.

As noted above, Gilead submits that one trial on all issues is appropriate under the circumstances, irrespective of whether the Court or a jury decides the inequitable conduct issues.

AbbVie's Position: AbbVie estimates a trial on the patent claims would take approximately ten (10) days, and seeks a trial during the period May to July 2016, as the Court's schedule permits. As noted in Section 4 above, AbbVie submits that inequitable conduct should be separately tried to the Court, and that, if Gilead's state law claims survive, those claims be separately tried following resolution of the inequitable conduct claims.

10. Jury trial

The parties have requested a jury trial on all issues so triable.

11. Settlement.

The parties believe that settlement discussions are premature at this juncture and agree to meet and confer during the fact discovery period.

12. Counsel for the parties have conferred about each of the above matters.

Exhibit A

Event	Gilead's Proposed Deadlines	AbbVie's Proposed Deadlines
AbbVie shall produce its infringement contentions	Gilead has served interrogatories on AbbVie seeking their contentions on infringement and seeks a response thereto in compliance with the Federal Rules of Civil Procedure and applicable case law.	January 26, 2015
Gilead shall produce its contentions specifying [redacted]	Gilead has responded to AbbVie regarding the [redacted] supplement those responses in compliance with the Federal Rules of Civil Procedure and applicable case law.	January 26, 2015[4]
Gilead shall produce its invalidity contentions	Gilead responded to AbbVie's discovery requests directed to invalidity and will supplement those responses in compliance with the Federal Rules of Civil Procedure and applicable case law.	February 25, 2015
Joinder of Other Parties	April 30, 2015	February 27, 2015
Amendment of Pleadings	June 30, 2015	February 27, 2015
Reliance Upon Advice of Counsel	Gilead shall inform AbbVie whether it intends to rely upon advice of counsel as a defense to willful infringement, and produce any such opinions on which Gilead intends to rely on or	Gilead shall inform AbbVie whether it intends to rely upon advice of counsel as a defense to willful infringement, and produce any such opinions on which Gilead intends to rely, and any related documents, on or

[4] AbbVie disagrees that Gilead has provided any substantive response to AbbVie's interrogatory relating to what [redacted] or to AbbVie's requests for Gilead's invalidity contentions.

Event	**Gilead's Proposed Deadlines**	**AbbVie's Proposed Deadlines**
	before June 30, 2015.	before February 25, 2015.
Rule 26(a) Initial Disclosures	Completed	Completed
Substantial Completion of Document Production	June 30, 2015	March 24, 2015
Close of Fact Discovery	October 30, 2015	June 24, 2015
Opening Claim Construction Brief Answering Claim Construction Brief Final Joint Claim Chart Markman Claim Construction Hearing	July 10, 2015 (two months in advance of hearing) August 7, 2015 (one month in advance of hearing) August 7, 2015 (one month in advance of hearing) September 2015 [requested]	April 7, 2015 May 7, 2015 May 7, 2015 June 2015 [requested]
Deadline for Service of Opening Expert Reports on which each party has the burden of proof	November 20, 2015	July 30, 2015
Deadline for Service of Rebuttal Expert Reports	December 23, 2015	September 30, 2015
Deadline for Service of Reply Expert Reports only in response to opinions on secondary considerations of non-obviousness, if applicable	January 29, 2016	October 15, 2015
Close of Expert Discovery	February 29, 2016	December 4, 2015
Summary Judgment Requests Opening Letter Briefs Answering Letter Briefs	March 7, 2016 April 7, 2016 April 28, 2016	December 9, 2015 December 23, 2015 January 6, 2015

Event	**Gilead's Proposed Deadlines**	**AbbVie's Proposed Deadlines**
Reply Letter Briefs		
Pretrial Order	3 weeks before pre-trial conference	3 weeks before pre-trial conference
Pretrial Conference	2 weeks before trial	2 weeks before trial
Trial	September 2016 [requested]	May - July 2016 [requested]

Respectfully submitted,

January 14, 2015

FISH & RICHARDSON P.C.

By: */s/ Gregory R. Booker*
Douglas E. McCann (#3852)
Gregory R. Booker (#4784)
222 Delaware Avenue
17th Floor
P.O. Box 1114
Wilmington, DE 19899
(302) 652-5070
dmccann@fr.com
booker@fr.com

Attorneys for Plaintiffs, Defendants, Counterclaim Plaintiffs and Third-Party Plaintiffs,

GILEAD SCIENCES, INC., GILEAD PHARMASSET LLC and GILEAD SCIENCES LIMITED

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

By: */s/ Mary B. Graham*
Mary B. Graham (#2256)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mgraham@mnat.com
dfahnestock@mnat.com

Attorneys for Defendant and Third-Party Defendants ABBOTT LABORATORIES, INC.

and

Attorneys for Defendant, Plaintiff and Counterclaim Defendant,
ABBVIE, INC.

SO ORDERED this _____ day of _____ 2015.

Honorable Gregory M. Sleet
UNITED STATES DISTRICT COURT JUDGE